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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,709	10/30/2003	Edward W. Merrill	37697-0080	6478

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PROSKAUER ROSE LLP
1001 PENNSYLVANIA AVE, N.W.,
SUITE 400 SOUTH
WASHINGTON, DC 20004

EXAMINER	
BERMAN, SUSAN W	
ART UNIT	**PAPER NUMBER**
1711	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/696,709	MERRILL ET AL.	
	Examiner	Art Unit	
	Susan W. Berman	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-134* is/are pending in the application.

4a) Of the above claim(s) *128-134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

Applicant's election with traverse of Group I in the reply filed on 06-20-2006 is acknowledged. The traversal is on the ground(s) that "melting" and "pre-annealing" are synonymous terms. This is not found persuasive because (1) if the terms were synonymous, the claims are directed to the same invention and, therefor, duplicative claims, (2) however, the terms are not synonymous because the term "pre-annealing" encompasses thermal treatment at various temperatures other than the melting temperature or temperatures above melting. The dictionary definition of "annealing" is heating a material (usually metal or glass) and cooling it slowly. See "anneal" in Webster's dictionary, Hawley's Chemical Dictionary or Hackh's Chemical Dictionary.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

The rejection of claim 124 under 35 U.S.C. 112, second paragraph, is withdrawn.

Response to Arguments

Applicant's arguments filed 06/29/2006 have been fully considered but they are not persuasive.

With respect to the previous withdrawal of the rejection of claims over Saum et al, the withdrawal was based on an effective filing date of 10/02/1996 being the same as the filing date of applicant's priority application 08/726,313 of 10/02/1996. It was not based on the filing date

of application 08/600,744 which is 02/13/1996. The instant claim language is not supported by the disclosure of 08/600,744.

With respect to the rejections under 35 USC 112, first paragraph, applicant submits that the claims are fully supported by the specification. This argument is not persuasive. Applicant has pointed to support for claiming "polyethylene heated at or above its melting temperature for about 5 minutes to about 3 hours and for heating to about 175^0C and cooling the heated and irradiated polyethylene. If applicant intends to rely on it being well-known that 175 ^{0}C is less than the decomposition temperature of UHMWPE, evidence to support the allegation and to identify the specific UHMWPE and its decomposition temperature should be made of record. However, even such evidence fails to provide support for temperatures other than 175 ^{0}C actually set forth in the specification as filed. With respect to the recitation "period of time greater than about 30 minutes", now "greater than 30 minutes", there is no recognition in the specification as filed that greater than 30 minutes is a significant time period.

With respect to the rejection of claims over Salovey et al: Applicant points to Declarations that are not of record in the instant application. It is not agreed that the instant claims are entitled to section 120 priority date of 02-13-1996 or 10-13-1996, since neither of the priority documents mentions "pre-annealing at a temperature greater than ambient temperature and less than the decomposition temperature of the polyethylene for a period of time greater than 30 minutes".

With respect to the instant claim recitation of "irradiating the polyethylene preform to crosslink the polyethylene preform" : Shalaby et al: The "low dose irradiation" or "sterilization irradiation" taught by Salovey et al is encompassed by the instantly claimed phrase "irradiating

the polyethylene preform". The claim phrase "to crosslink the polyethylene preform" is a statement of intended purpose and not a patentable weight. Furthermore, irradiation as taught by Salovey et al would be expected to crosslink the polyethylene, in the absence of evidence to the contrary. The irradiation for sterilization taught by Shalaby et al or Sun et al is also encompassed by the instantly claimed phrase "irradiating the polyethylene preform". The claim phrase "to crosslink the polyethylene preform" is a statement of intended purpose and not a patentable weight. Furthermore, irradiation as taught by Shalaby et al or Sun et al would be expected to crosslink the polyethylene, in the absence of evidence to the contrary. That chemical crosslinking is also taught by Shalaby et al or heat-treatment for crosslinking by Sun et al does not negate the teaching of irradiation.

Applicant's argument with respect to the double patenting rejections of record are unpersuasive. See the reasons for the rejections set forth in the rejections.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-127 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has not found any disclosure of "pre-annealing" or "at a temperature greater than ambient temperature and less than the decomposition temperature" or for a "period of time greater than about 30 minutes" of polyethylene. The examiner has not found any disclosure of "quenching residual free radicals" in the polyethylene perform. The examiner has not found any disclosure of cooling after the "quenching step" to a "temperature below the melting temperature" of the polyethylene. Applicant is reminded that claim language should correspond to the description as filed.

US 5,879,400 discloses a method wherein polyethylene is "heated at or above its melting temperature" for a "period of about 5 minutes to about 3 hours", followed by irradiation to crosslink, cooling at a rate equal to or greater than about 0.5^0 C/min., and is then machined or compression molded (column 2, lines 30-52). The examples disclose heating to about 175^0C and holding at the steady state temperature for 30 minutes before starting irradiation, followed by irradiation and cooling at a rate of about 0.5^0 C/min. and then by machining.

US SN 08/726,313, filed 10-02-1996, includes the disclosure of melt irradiation set forth in US '400 and also discloses variations on irradiation (warm or cold) followed by melting so that there are substantially no detectable free radicals. The method of WIR-SM includes pre-heating UHMWPE to a temperature below the melting point, irradiation and subsequent melting. This disclosed method appears to be closest to the instantly claimed method but fails to provide support for the wording used in the instant claims. There is no mention of pre-annealing, decomposition temperature, quenching, time period greater than about 30 minutes.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 124 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 124, the phrase "greater than about 30 minutes" is indefinite because it is not clear whether applicant intends to claim a "time greater than 30 minutes" or a "time of about 30 minutes".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Salovey et al (6,281,264, having an effective filing date of 01/20/1995). Salovey et al teach a method for crosslinking UHMWPE for forming in vivo implants. The method comprises irradiation crosslinking of a molten polymer. See column 3, lines 50-59, column 4, line 42, to column 5, line 66, column 11, line 38, to column 12, line 11, column 13, lines 44-54. Salovey et al report the effects of the disclosed method on % crystallinity.

Claims 124-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411). Shalaby et al disclose a method that comprises melting an UHMWPE "construct polymer-fiber" and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE. See column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 124-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049). Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant. The irradiated implant is then further annealed to reduce free radicals. The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a perform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition temperature is considered to encompass the melting step set forth in the claims of '440. Alternatively, the melting step set forth in the claims of '440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims of '440 encompasses the pre-annealing step in the instant claims. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. With resepct to claims 126-127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '089 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Berman

SB
12/26/2005

Susan W Berman
Primary Examiner
Art Unit 1711

WILLIAM GARY JONES
DIRECTOR
TECHNOLOGY CENTER 1700